Technology Assessment and Adoption in Orthopaedics: Lessons Learned

The rising cost and variable quality of health-care delivery in the U.S. have become the subject of great debate among policymakers, providers, payers, and patients. Although health-policy experts and health-care researchers have identified numerous factors that contribute to rising costs, there is widespread agreement that the adoption and use of new health-care technologies are a major contributor to escalating health-care costs in the U.S. In addition to concerns about cost, the introduction of new medical technologies raises questions related to quality and safety, including how to minimize complications during the “learning curve” period through appropriate training and/or credentialing, how to appropriately communicate potential risks associated with new interventions to patients, and who should be responsible for postmarket surveillance and reporting.

Over the past half century, the introduction of many orthopaedic technologies, including the Charnley low-friction arthroplasty, arthroscopy, and internal fixation devices for the treatment of fractures, has led to important advances in patient care. However, there are also numerous examples of orthopaedic technologies that were introduced with great enthusiasm and optimism but unfortunately did not perform as well in clinical practice as they had in the laboratory setting, in some cases resulting in poor patient outcomes and high rates of unanticipated complications. Furthermore, the widespread adoption of new, more costly orthopaedic technologies has resulted in a substantial increase in the overall cost of care associated with orthopaedic procedures.

Orthopaedic technologies are frequently introduced into the marketplace, often at a substantially higher cost, despite limited evidence of their effectiveness in comparison with the gold-standard technology or procedure. Furthermore, there is a paucity of well-designed clinical trials comparing new orthopaedic technologies with the gold-standard treatment and, as a result, the quality of evidence related to the safety, efficacy, and cost-effectiveness of many new orthopaedic techniques and/or devices is often poor compared with that in other disciplines. There are many reasons for this, including ethical, logistical, and economic challenges associated with the performance of prospective, randomized controlled trials related to surgical procedures; the long duration of follow-up needed to evaluate clinically relevant outcomes in orthopaedics; and a lack of incentive for surgeons, hospitals, and device companies to evaluate and report the performance of new technologies after they have been approved by the U.S. Food and Drug Administration and have been released into the marketplace. Given the logistical and economic challenges associated with randomized controlled trials of medical devices, clinicians, patients, and policymakers should look beyond such trials to other sources of information when evaluating new technologies. Well-designed observational cohort studies, decision analysis models, medical device registries, and administrative databases can all provide valuable insights into the utilization, clinical efficacy, safety, and cost-effectiveness of new medical devices.

Valuable insights have been presented in this issue of *The Journal* by Anglen and Weinstein and by Forte et al., who used data from the American Board of Orthopaedic Surgery and Medicare Provider databases regarding variation in practice patterns in the treatment of intertrochanteric hip fractures. Both groups of authors pointed out that, despite a lack of convincing evidence regarding the benefits of intramedullary nails for the treatment of intertrochanteric hip fractures, the use of these devices has increased substantially over the past decade. The article by Forte et al. also provides evidence of widespread regional variation in practice patterns, with the rates of intramedullary nail use differing by more than tenfold among states. This type of regional variation in practice patterns, which was reported previously by Wennberg and others and is common throughout our health-care system, highlights the lack of consensus regarding the appropriate treatment for intertrochanteric hip fractures. This further underscores the need for better evidence in the form of comparative trials to...
in its newness but rather in its ability to improve patient outcomes, reduce morbidity, and/or reduce the overall cost of care. Orthopaedic surgeons and device manufacturers should seek out opportunities to work collaboratively with other stakeholders in the health-care system to improve the quality of information available regarding the safety, efficacy, and cost-effectiveness of new orthopaedic technologies both before and after they are introduced into clinical practice. Our professional organizations can play a major role in this effort through the development of high-quality, unbiased evidence-based clinical practice guidelines, advocacy for the establishment of national device registries (modeled after successful joint replacement registries in Northern Europe, Australia, and elsewhere), and development and dissemination of evidence-based technology assessments. Repeated surveys of the fellows of the American Academy of Orthopaedic Surgeons have demonstrated strong support for this organization’s involvement in providing timely technology assessments to its members. Better information about the comparative effectiveness and cost of new devices and interventions will become ever more important in an era of increased transparency of quality and cost information and increased emphasis on the efficient management of scarce health-care resources.

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References